

Please find below and/or attached an Office communication concerning this application or proceeding.

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A:\>DIR

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AXM41S~1 TXT

78,445 04-15-02 11:58a axm4.1seqs.txt

1 file(s)

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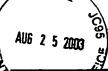
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#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

ART UNIT:

**EXAMINER:** 

1648

Salimi, Ali Reza

Schubart et al.

Serial No.:

09/981,397

Filed:

October 16, 2001

Entitled:

CELLULAR KINASES INVOLVED IN

CYTOMEGALOVIRUS INFECTION AND

THEIR INHIBITION

Attorney Docket No.: AXM-004.1 US

**Mail Stop Petition** 

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Sir:

Transmitted herewith: [X] an Amendment accompanying a Petition under 37 CFR §1.78(a)(6); [X] a check (no. 4707) in the amount of \$1-300.00 in payment of the fees under 37 CFR § 1.17(t); [X] a Petition Under 37 C.F.R. §1.78(a)(6) To Accept An Unintentionally Delayed Claim To Priority Under 35 U.S.C. §119(e); and [X] a returnreceipt postcard, for filing in-the above-captioned patent application.

The commissioner is hereby authorized to charge payment of any additional fees required in connection with the paper(s) transmitted herewith, or to credit any overpayment of same, to Deposit account no. 50-0268. A duplicate of this transmittal letter is submitted herewith.

Respectfully submitted,

Leon R. Yankwich, Reg. No. 30,237

Michael R. Wesolowski, Reg. No. 50,944

Applicants' Representatives Yankwich & Associates

201 Broadway

Cambridge, MA 02139

Telephone: (617) 374-3700 Facsimile: (617) 374-0055

CERTIFICATE OF MAILING BY "EXPRESS MAIL"

The undersigned hereby certifies that this correspondence listed above is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" Service under 37 CFR §1.10, postage prepaid, in an envelope addressed to Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.

Express Mailing Label No.: EV 325775053

1



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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## TRANSMITTAL LETTER

Sir:

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AUG 2 8 2003

DUPLICATE



Application of:

Schubart et al.

Serial No.:

09/981,397

Filed:

October 16, 2001

Entitled:

CELLULAR KINASES INVOLVED IN

CYTOMEGALOVIRUS INFECTION AND

THEIR INHIBITION

Attorney Docket No.: AXM-004.1 US

**Mail Stop Petition** 

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## AMENDMENT ACCOMPANYING PETITION UNDER 37 C.F.R. §1.78(a)(6)

Sir:

This amendment requests entry of a statement claiming priority to a prior-filed provisional application and is accompanied by a petition submitted pursuant to 37 C.F.R. §1.78(a)(6) requesting acceptance of the unintentionally delayed claim to priority for the above-referenced application.

The present amendments follow the revised format procedure mandated in 68 Fed. Reg. 38611, published June 30, 2003.

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1648

Salimi, Ali Reza

ART UNIT:

**EXAMINER:** 

AUG 2 8 2003

## AMENDMENTS TO THE SPECIFICATION

(Amendments are illustrated by showing deletions by strikethrough and additions by underlining)

1. Below the Title of the Application and before the heading "Specification" on page 1 of the application, please insert the following new paragraph:

## -- Cross Reference to Related Applications

This application claims priority to United States provisional application serial number 60/240,750, filed October 16, 2000.--

## REMARKS

The above-referenced application was filed under 35 U.S.C. §111(a) with the United States Patent & Trademark Office on October 16, 2001 and claimed priority to pending provisional application 60/240,750, filed October 16, 2000.

The application correctly claimed priority to pending provisional application no. 60/240,750 in the combined declaration/power of attorney; however, the specification was inadvertently never amended to contain the statement referencing the prior-filed application as mandated in 37 C.F.R. §1.78(a)(5)(i) and 35 U.S.C. §119(e). Therefore, Applicants submit this amendment and accompanying petition pursuant to 37 C.F.R. §1.78(a)(6) requesting entry of the stated reference claiming priority to the provisional application according to 37 C.F.R. §1.78(a)(5)(i) and 35 U.S.C. §119(e).

Respectfully submitted,

Leon R. Yankwich (Reg. No. 30,237)

Michael R. Wesolowski (Reg. No. 50,944)

Applicants' Representatives

YANKWICH & ASSOCIATES

201 Broadway

Cambridge, Massachusetts 02139

telephone: (617) 374-3700 telefax: (617) 374-0055

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Express Mailing Label No.: EV 32577

Stephanie Leicht

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AUG 2 8 2003

910 Office Action Summary

Application No.

09/981,397

Schubart et al

Examiner

A. R. SALMI

Art Unit 1648

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The MAILING DATE of this communic	ation appears on the cover sheet with the correspondence	e address
Period for Reply		
mailing date of this communication.  If the period for reply specified above is less than thirty (30) day	FION.  CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6), s, a reply within the statutory minimum of thirty (30) days will be considered.	) MONTHS from the
<ul> <li>Failure to reply within the set or extended period for reply will, b</li> </ul>	period will apply and will expire SIX (6) MONTHS from the mailing date of thing statute, cause the application to become ABANDONED (35 U.S.C. § 133), we mailing date of this communication, even if timely filed, may reduce any	is communication.
Status		
1) 🕅 Responsive to communication(s) filed (	on <i>Jun 9, 2003</i>	
2a) This action is <b>FINAL</b> . 2b	▼ This action is non-final.	
3) Since this application is in condition for closed in accordance with the practice	allowance except for formal matters, prosecution as under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213	s to the merits is
Disposition of Claims	210 21 parts dayley 1000 015. 11, 400 016. 210	,. 
4) 💢 Claim(s) <u>1-28</u>	is/are pending	in the application.
4a) Of the above, claim(s) 2-19 and 22-	28 is/are withdra	awn from consideration.
5)  Claim(s)	is/are allo	
	is/are rej	ected.
7)	is/are obj	•
	are subject to restriction and/	· · · · · · · · · · · · · · · · · · ·
Application Papers		
9) $\square$ The specification is objected to by the	Examiner.	
10) X The drawing(s) filed on Oct 16, 200	is/are a) X accepted or b) □ objected to by the	he Examiner.
	ction to the drawing(s) be held in abeyance. See 37 CFR	
	onis: a)□ approved b)□ disa	pproved by the Examiner.
If approved, corrected drawings are requ	•	
12) The oath or declaration is objected to b	y the Examiner.	
Priority under 35 U.S.C. §§ 119 and 120  13) Acknowledgement is made of a claim f		
	or foreign priority under 35 U.S.C. § 119(a)-(d) or (f).	,
_	umanta hava hava a	
	uments have been received in Application No.	
	ne priority documents have been received in this National Bureau (PCT Rule 17.2(a)).  Talist of the certified copies not received.	onal Stage
	or domestic priority under 35 U.S.C. § 119(e).	
a) $\square$ The translation of the foreign language	e provisional application has been received.	
15)□ Acknowledgement is made of a claim fo Attachment(s)	or domestic priority under 35 U.S.C. §§ 120 and/or 1	21. RECEIVE
1) Notice of References Cited (PTO-892)	4) Interview Summary (PTO-413) Paper No(s).	
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) Notice of Informal Patent Application (PTO-152)	- AUG 2 8 2003
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s).	11 6) Other:	OFFICE OF PETITION

# Notice of References cited

Application/Control No. 09/981,397

Applicant(s)/Patent Under Reexam Schubart et al

Examiner

A. R. SALMI

Art Unit

1648

Page 1 of 1

**U.S. PATENT DOCUMENTS** 

	Document Number Country Code-Number-Kind Code 6211337B1	Date 9	Name	Clas	sification <sup>2</sup>
. А	6211337B1	4/2001	Baichwal et al	530	350
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### FOREIGN PATENT DOCUMENTS

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		Document Number Country Code-Number-Kind Code	Date MM-YYYY <sup>1</sup>	Country	Name	Classification <sup>2</sup>
	N	WO 00/011218 A1	3/2000	wo	Gingeras et al	
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	Q			-		
	R					
	s					
	Т					

## NON-PATENT DOCUMENTS

L		Include, as applicable: Author, Title, Date, Publisher, Edition or Volume, Pertinent Pages
	U	Zhu et al , PNAS USA, 1998, Vol. 95, pp. 14470-14475.
	v	
	w	
	x	

<sup>\*</sup> A copy of this reference is not being furnished with this Office action. See MPEP § 707.05(a).

<sup>&</sup>lt;sup>2</sup> Classifications may be U.S. or foreign.

Modified FORM PTO-1449	ATTY. DOCKET AXM-004.1 U	<b>SERIAL NO.</b> 09/ 981,397
LIST OF PATENTS AND PUBLICATIONS ROR APPLICANT'S INFORMATION DISCLESSURE STATEMENT	APPLICANT Schubart et	al.
(Use several sheets it necessary)	FILING DATE October 16, 2001	RECEINAUID 1646
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REFERENCE DESIGNATION

U.S. PATENT DOCUMENTS

TECH CENTER 1600/2900

REFERENCE DESIGNATION OF U.S. PATENT DOCUMENTS   EUN UENTEN 1000/							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
A.S	AA	US 5,242,974	9/7/93	Holmes	_		
	AB	US 5,384,261	1/24/95	Winkler et al.			
	AC	US 5,405,783	4/11/95	Pirrung et al.			
	AD	US 5,412,087	5/2/95	McGall et al.			
	AE	US 5,424,186	6/13/95	Fodor et al.			
	AF	US 5,429,807	7/4/95	Matson et al.			
	AG	US 5,436,327	7/25/95	Southern et al.			
	AH	US 5,445,934	8/29/95	Fodor et al.		<u>-</u>	
	Al	US 5,472,672	12/5/95	Brennan			
	AJ	US 5,527,681	6/18/96	Holmes			
	AK	US 5,529,756	6/25/96	Brennan		_	
	AL	US 5,545,531	8/13/96	Rava et al.			
	AM	US 5,554,501	9/10/96	Coassin et al.			
	AN	US 5,556,752	9/17/96	Lockhart et al.			
	AO	US 5,561,071	10/1/96	Hollenberg et al.			
	AP	US 5,599,895	2/4/97	Heider	·		
	AQ	US 5,624,711	4/29/97	Sundberg et al.			
	AR	US 5,639,603	6/17/97	Dower et al.			
	AS	US 5,658,734	8/19/97	Brock et al.			
	AT	US 5,807,522	9/15/98	Brown et al.			
J	AU	US 6,087,102	7/11/00	Chenchik et al.			

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	TRANSL YES	ATION NO
A	AV	JP 11189529 A	7/13/99	Toray Ind. Inc.				
B	AW	JP 11124368 A	5/11/99	Takeda Chem. Ind. Ltd.				
EXAMINER A W3		DATE CONSII	DERED	7/7/0	3			

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP §609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

sheet \_\_1\_ of \_\_3\_\_

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	<i>A</i> ://		
uified FORM PTO-1449	70T 5 3 5005 5	ATTY. DOCKET AXM-004.1 U	<b>SERIAL NO.</b> 09/981,397
LIST OF PATENTS AND PUBLICATE APPLICANT'S INFORMATION DISC STATEMENT	NS FOR LOSSIFIED TO	APPLICANT Schubart	et al.
(Use several sheets) necess	sary)	FILING DATE October 16, 2001	1646 JUL 2 5 2002
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TECH CENTER 1600/2900 OREIGN PATENT DOCUMENTS (cont'd) TRANSLATION DOEMMENT NUMBER NAME CLASS SUBCLASS DATE YES AX JP 9183764 A 7/15/97 Morishita Roussel KK AY WO 93/17126 9/2/93 Chetverin et al. ΑZ WO 95/11995 5/4/95 Chee et al. BA WO 95/35505 12/28/95 Shalon et al BB EP 742 287 11/13/96 McGall et al. BC EP 799 897 10/8/97 Morris et al. BD WO 97/02039 1/23/97 Rossi et al.

11/5/98

6/1/99

11/4/99

12/23/99

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

Guy et al.

Miller et al.

Arnold et al.

Chowers et al.

M	BI	Bell et al., British J. Cancer, 77:1852-1856 (1998)		
	BJ	Bhagwat et al., <i>DDT</i> , 4:472-479 (1999)		
	ВК	Blank et al., J. Biol. Chem., 27:5361-5368 (1996)		
	BL	Goekjian, et al., Curr. Med. Chem., 6:877-903 (1999)		
	ВМ	Goldenberg, Clinical Therapeutics, 21:309-318 (1999)		
	BN	Hughes et al., <i>Proc. Natl. Acad. Sci</i> , 87:6728-7-6732 (1990)		
EXAMINE	R Ay	DATE CONSIDERED 7/7/03		

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP §609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

sheet \_\_2\_ of \_\_3\_\_

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WO 98/48836

WO 99/32463

WO 99/55335

WO 99/65513

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Modified FORM PTO-1449	ATTY. DOCKET AXM-004.1	<b>SERIAL NO.</b> 09/981,397
APPLICANT'S INFORMATION DISCLOSURE STATEMENT	APPLICANT Schubart et al.	RECEIVED
(Use several sheets if necessor)	FILING DATE October 16, 2001	GROUP JEH6 2 5 2002
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		OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)
B	ВО	Keates et al., J. Immunol., 163:5552-5559 (1999);
	BP	Kuroyanagi et al., Biochem. Biophys. Res. Commun., 242:357-364 (1998);
	BQ	Marshall, Science, 286:444-447 (1999);
	BR	Mitamura et al., J. Biol. Chem., 270:1015-1019 (1995);
	BS	Naumann et al., J. Biol. Chem., 274:31655-31662 (1999);
	ВТ	Prenzel et al., Nature, 402:884-888 (1999)
	BU	Raingeaud et al., Mol. Cell. Biol., 16:1247-1255 (1996);
	BV	Revel et al., Drugs of the Future, 23:751-766 (1998);
	BW	Service, Science, 289:1673;
	BY	Tarnawski et al., J. Clin. Gastroenterol., 27(Suppl. 1):S12-S20 (1998);
	BZ	Traxler et al., Drugs of the Future, 20:1281-1274 (1995);
	CA	Wang et al., J. Cell. Biol., 140:737-750 (1998);
	СВ	Wang et al., <i>Genomics</i> , 57:310-315 (1999);
· V	СС	Wojtowitz-Praga et al., Investig. New Drugs, 15:61-75 (1997);
A\$	CD	Wysk et al., <i>PNAS USA</i> , 96:3763-3768 (1999)
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EXAMINER	Ar	DATE CONSIDERED 7/7/03

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Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant

sheet \_3\_ of \_3\_

Art Unit: 1648

### **DETAILED ACTION**

### Election/Restriction

Applicant's election with traverse of Group I (claims 1, 20, 21 within the scope of SEQ ID NO: 16) in Paper No. 15 is acknowledged. The traversal is on the ground(s) that the embodiments of the invention share common features, and fractionation of the claims would lead to repetitive examination and undue expense. In addition, applicants argue that no undue search would be required because the groups are classified in one class i.e. 435. Applicants further argue the claims of Groups I-III, V and VI would reveal the same art. This is not found persuasive because, applicants provide no evidence that indicates the search would reveal the same art. Group I is directed to identifying agents, Group II is directed to detection of cytomegalovirus, etc..., detecting cytomegalovirus infection and agents are vastly different one from the other. In addition, classification of subject matter is merely one indication of the burdensome nature of the search involved. Still further, the subclass within the classified group are vast. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden search. The various kinases have different structures they are distinct one from the other. Applicants do not present argument to the contrary. Clearly different searches and issues are involved in the examination of each group. As for the assertion regarding undue expense, applicants are reminded that the expense is a business decision and has no bearing on the burdensome search.

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The requirement is still deemed proper and is therefore made FINAL.

Claims 2-19, 22-28 are withdrawn from further consideration pursuant to 37 CFR

Page 3

1.142(b), as being drawn to a nonelected Groups, Applicant timely traversed the restriction

(election) requirement in Paper No. 15. Applicants are reminded that the elected claims 1, 20, and

21 have been examined only within the elected SEQ ID NO: 16, RIP kinase

Applicants are reminded to cancel the claims to the non elected claims.

**Priority** 

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Please note the claims are generally narrative and indefinite, failing to conform with current U.S.

practice. They appear to be a literal translation into English from a foreign document and do not

conform with current U.S. practice. The correction is respectfully requested.

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# Claim Rejections - 35 USC § 112

Claims 1, 20, and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite for recitation of "associated diseases", what are the associated diseases? Is migraine an intended associated disease? In addition, the claim is vague and indefinite for recitation of "change in activity" this is a relative terminology, what applicants deem to be a change might not be a change. How is the "change" determined, visually, or chemically? Moreover, is the increase in activity or decrease in activity of the kinases that determines a compound as a viable candidate for treating or preventing cytomegalovirus infection? How much change is to be deemed as a base for determining whether or not a compound is useful? Still further, the claim is very confusing, because the method does not set forth any step(s) for how the measuring is/are determined, and sufficient steps that would allow the practice of the claimed invention. There are so many variables present that one of skill in the art would not know what to add, when to add, what to measure, and when to measure? Shouldn't there be a control of some sort present? Is the kinase within the cell or is the kinase sequence by itself being utilized? Is the compound measuring changes in infected cells or noninfected cells? Is the compound as such that binds to the kinase or inhibits it expression or what is the compound suppose to do? How does change of activity relate to treating or preventing

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cytomegalovirus? Are the kinase gene the intended targets or its protein? Are the kinases down regulated by the cytomegalovirus or up regulated? Please clarify?

Claims 20, and 21 are vague and indefinite the intended oligonucleotide or kinases should be identified by a specific sequence identification number. In addition, the claims are vague and indefinite since no conditions are present which would allow the appropriate screening to take place. How can one know whether or not a compound is useful when no direction is given? Is the compound suppose to kill cells or bind the kinase or inhibit its expression?

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 20, and 21 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Zhu et al (PNAS USA, 1998, Vol. 95, pp. 14470-14475).

The claims are directed to utilizing cellular expression of kinase Rip in determining compounds that maybe useful in treating cytomegalovirus. Zhu et al already provided ample teaching in the above cited article about the method and assay of utilizing Rip kinase in

Page 6

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determination of cytomegalovirus infection. Zhu et al taught that when cells are infected with cytomegalovirus certain genes such as Rip kinase is up regulated and detection of such activity would lend itself in detecting compounds that would be useful in treating cytomegalovirus infection (see the entire document, especially the abstract, and Table 1, page 14472, bottom of left column).

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 20, and 21 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Gingeras et al (WO 00/011218 A1).

The above cited reference anticipates the now claimed invention. Gingeras et al taught the method and assay of utilizing Rip kinase in determination of cytomegalovirus infection and screening for compounds (see the abstract, see pages 38-42, and all claims especially claim 3).

Art Unit: 1648

Claim Rejections - 35 USC § 102

Page 7

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the

basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention

thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999

(AIPA) do not apply to the examination of this application as the application being examined was

not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b).

Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the

AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 20, and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by

Baichwall et al (US Patent No. 6,211,337 B1).

The claims and teaching of the above cited art anticipates the now claimed invention. The

method and assay disclosed in above cited patent clearly anticipates the now claimed invention.

Applicants' invention is directed in looking at and are targeting "activity" of RIP kinase. The

above cited patent also directed a method that measured interaction of RIP. Baichwall et al taught

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and claimed utilization of Rip kinase in screening for an agent which would target RIP kinase (see

Page 8

claim 3, and column 4, lines 8-27). Applicants are reminded that the in-house sequence search has

reveled SEQ ID NO: 2 as disclosed by Baichwall et al being 100% identical to the

SEQ ID NO: 16 that is being utilized in the method and assay of now claimed invention.

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (703) 305-7136. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 305-3014, or (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A. R. Salimi

7/18/2003

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